

Application No. 09/912,559
Attorney Docket No. 06478.1457-00

REMARKS

Resubmission of the Replacement Abstract

The Office first requests that Applicants re-submit the replacement abstract filed on September 10, 2003, changing the heading above the abstract's text to recite simply "Abstract." Applicants hereby comply with that request and make a few grammatical changes. As the actual substance of the abstract is identical to that submitted previously, this amendment should allow for immediate attention. Applicants respectfully request its entry under 37 C.F.R. § 1.116.

Status of the Claims

Claims 1-36 are pending in this application. The Office considers the subject matter of claims 2 and 33 to be allowable, rejects claims 1, 30-32, and 34-36, and has withdrawn claims 3-29.

Applicants present several claim amendments to speed prosecution of the application. First, Applicants cancel the withdrawn claims 3-29, as well as claims 1, 30, and 36. Second, Applicants amend claims 2, 31, 33, and 34 solely to make them independent or to change their dependency in light of the cancellation of claim 1. Finally, Applicants slightly change the wording of claims 32 and 35 according to the Office's request, as discussed below.

Applicants submit that these amendments place this application in condition for allowance, and respectfully request their entry under 37 C.F.R. § 1.116. Further, the proposed amendments do not raise new issues, present new matter, or require any additional search of the art, since all of the elements claimed were inherent in the claims

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as examined. Therefore, these claim amendments should allow for immediate action. Applicants also submit that the entry of the amendments would place the application in better form for appeal, should the Office continue to dispute the patentability of the pending claims.

Claims 31-32 and 34-35 Are Supported by the Application

The Office rejects claim 1 and its dependents, claims 30-32 and 34-36, contending that these claims lack written description support under 35 U.S.C. § 112, first paragraph. (Office Action at pages 2-5.)

Applicants traverse this rejection, and note that, upon entry of Applicants' proposed amendments, the rejection is moot as to claims 1, 30, and 36, and the phrase "polypeptide with FSAP activity."

The Office also contends that claim 31 is not supported in the application as filed. (Office Action at page 4.) The Office contends that the application supports a polynucleotide sequence with a single mutation at position 1601, and its corresponding G534E mutant protein, and supports a polynucleotide sequence with a double 1601 and 1177 mutation, and its corresponding G534E/E393Q mutant protein, but does not support a single 1177 or E393Q mutant. (*Id.*)

One of ordinary skill in the art, however, would find ample support in the application for a single G to C base exchange at 1177 and its corresponding E393Q mutant. See for example, page 6, in the paragraph immediately below Table 2. Here, Applicants state that the "invention thus relates to a mutant of the DNA sequence coding for the protease (FSAP) . . . which mutant comprise[s] a G/C base exchange at

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nucleotide position 1177 **and/or** a G/A base exchange at nucleotide position 1601."

The use of "and/or" in such a sentence is a clear signal to those of ordinary skill in the art that the invention encompasses a single 1177 mutation, as well as a single 1601 mutation and double 1177/1601 mutation.

Further, similar language is found in original claim 1, reciting "**at least one of a G to C** base exchange at nucleotide position 1177 and a G to A base exchange at nucleotide position 1601." This is merely a different way of expressing the 1177 "and/or" 1601 language at page 6 of the specification.

Thus, the Office rejects claim 31 based on the subject matter that it incorporates from original claim 1. The M.P.E.P. points out that written description rejections of such originally claimed material "should be rare" and that there is a "strong presumption that an adequate written description of the claimed invention is present in the specification as filed." M.P.E.P. §§ 2163(I)(A) and 2163.03; citing *In re Wertheim*, 191 U.S.P.Q. 90, 96 (C.C.P.A. 1976).

As an aside, the Office supports some of its assertions about the activities of the instant FSAP mutants by using two articles by Römisch and Willeit that were published well after this application was filed on July 26, 2001. (Office Action at pages 3-4, citing Römisch et al., *Blood Coagulation and Fibrinolysis*, 13: 433-441 (2002) and Willeit et al., *Circulation*, 107: 667-670 (2003).) A written description rejection is considered based on the knowledge of one of ordinary skill in the art *at the time the application was filed*; not at some later period in time. Thus, written description, or lack thereof, cannot be supported using later publications that show the knowledge in the art at some later date

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after further discoveries have been made. See, e.g., *In re Mott*, 190 U.S.P.Q. 536, (C.C.P.A. 1976); *In re Koller*, 204 U.S.P.Q. 702 (C.C.P.A. 1980).

Applicants respectfully request the withdrawal of this rejection in light of the preceding amendments and remarks.

Claims 31-32 and 34-35 Are Enabled

The Office also rejects claim 1 and its dependent claims 30-36, asserting that the claims are not enabled under 35 U.S.C. § 112, first paragraph. (Office Action at pages 5-8.)

As this rejection appears to be directed solely at claim 1, Applicants submit that the rejection is moot upon entry of the present amendments which cancel that claim. Further, the sequence listings and other information in the instant application provide ample guidance for one of ordinary skill in the art to make and use the polynucleotide sequences of claims 31-32 and 34-35. Thus, Applicants request the entry of the amendments and the withdrawal of this rejection.

Claims 2 and 31-35 Are Definite

Finally, the Office contends that several claims are indefinite under 35 U.S.C. § 112, second paragraph. (Office Action at pages 8-9.)

First, the Office objects to the phrase "a polypeptide with FSAP activity" in claim 1 and dependent claims 2 and 30-36. (Office Action at page 8.) Second, the Office objects to another phrase in claim 1 that "nucleotide positions 1177 and 1601 are defined with reference to SEQ ID NO:1." Third, the Office contends that claim 34 is broader than claim 1. (Office Action at page 9.) Fourth, the Office contends that claim

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36 is indefinite. (*Id.*) The instant amendments cancel both claims 1 and 36, rendering all of these rejections moot. Thus, Applicants request the entry of the amendments and the withdrawal of these four rejections.

Finally, the Office asserts that claim 32 is unclear because it uses the term "comprises," and that this wording renders claim 31 indefinite. (Office Action at page 9.) Applicants amend claim 32 to recite that "the nucleotide at position 1601 is an A," thus removing the word "comprises" from claim 32. Hence, claims 31 and 32 are definite, and Applicants request the withdrawal of this rejection.

CONCLUSION

In view of the foregoing remarks, Applicants submit that this application is in condition for allowance. Applicants respectfully request the entry of the amendments and the allowance of claims 2 and 31-35.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: February 24, 2004

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Attachments: Abstract

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